
Section 5: 510(k) Summary

(Revised April 28, 2014)

CARESCAPE Central Station

510(K) SUMMARY

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: December 20th, 2013

Submitter: GE Medical Systems *Information Technologies,* Inc.
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Milwaukee, WI 53223

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Device Trade Name: CARESCAPE Central Station (formally known as CIC Pro)

Common/Usual Name: Central Station

Classification: 21 CFR 870.2450

Product Code: DXJ

Secondary Codes:
BZQ 21 CFR 868.2375 monitor, breathing frequency
CBR 21 CFR 868.1700 analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
CBS 21 CFR 868.1620 analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
CBQ 21 CFR 868.1500 analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)
CCK 21 CFR 868.1400 analyzer, gas, carbon-dioxide, gaseous-phase
CCL 21 CFR 868.1720 analyzer, gas, oxygen, gaseous-phase
DXN 21 CFR 870.1130 system, measurement, blood-pressure, noninvasive
DOA 21 CFR 870.2700 oximeter
DPT 21 CFR 870.2300 monitor, cardiac (incl. cardiotachometer & rate alarm)
DSB 21 CFR 870.2770 plethysmograph, impedance
DSK 21 CFR 870.1110 computer, blood-pressure
GWQ 21 CFR 882.1400 full-montage standard

electroencephalograph
FLL 21 CFR 880.2910 thermometer, electronic, clinical
NHO 21 CFR 868.1500 analyzer, gas, desflurane, gaseous-phase (anesthetic concentration)
NHP 21 CFR 868.1500 analyzer, gas, sevoflurane, gaseous-phase (anesthetic concentration)
NHQ 21 CFR 868.1500 analyzer, gas, isoflurane, gaseous-phase (anesthetic concentration)
BSE 21 CFR 868.1640 Helium gas analyzer
JEG 21 CFR 868.1075 Argon gas analyzer
CCI 21 CFR 868.1690 Nitrogen gas analyzer

Predicate Device(s): CIC Pro Clinical Information Center (K062976)
MUSE ST Guard (K842308)
12SL V22 – ACS (K092369)
MUSE CV (K110132)

Device Description: The CARESCAPE Central Station (CSCS) is based on a PC technology platform and is user friendly for easy operation using a simple logical screen menu. The interactive controls include the use of a computer mouse and keyboard and optional touch screen. Optional writers for the purpose of graphing waveforms and printing patient information include a 2-inch Direct Digital Writer and/or a laser printer. Internal and external speakers provide alarm audio indication.

The CSCS provides centralized monitoring of patients connected to GE Medical Systems *Information Technologies'* monitors and telemetry transmitters. It may be configured to display up to four real-time waveforms per patient for up to 16 patients and up to 9 waveforms for a single selected patient. Waveforms include ECG, SPO2, respiration ventilation flow and pressure, invasive blood pressure and CO2.

Patients may be admitted to and discharged from monitors and telemetry devices from the central location. The central station is also the control and display device for telemetry monitoring. Patient demographic information, including medical record number and patient name made be entered and modified.

The display window for each patient shows waveforms and vital information including: patient name, bed number, arrhythmia and alarm visual indicators, system messages, audio pause indicator, audio alarm indicator, alarm message line, heart rate, PVC count, transmitter number, ECG lead label,

pacemaker status, ST measurement, and graph status. Physiological parameters and waveforms from the GE Medical Systems *Information Technologies'* monitors can be displayed and printed from the CSCS.

Non-real time patient information available for reviewing and printing includes: Graphic Trends, Tabular Numeric Vital SignsTrends, Event HistoryReview, Full Disclosure, Calipers, and ST Review. Data can be printed to a networked laser printer. In the case of Event Review, data can also be printed to a PDF file.

The CARESCAPE Central Station also provides remote control of patient monitor and telemetry device configuration settings that includes:

- Admitted patient demographics like name and medical record number;
- Alarm Settings like high/low limit values and alarm priority levels;
- Printing settings like selection of which waveforms to print on graphs and the printed output destinations;
- ECG settings like primary lead selection, ST analysis on/off and pace maker detection on/off;
- Initiate and terminate combination monitoring where a bedside patient monitor accepts ECG data from a telemetry transmitter;
- Non-ECG parameter settings like respiration lead selection and NBP cuff size selection.

The CSCS provides secondary annunciation of alarms from primary bedside monitoring devices and primary annunciation of alarms from wireless telemetry devices.

The Full Disclosure option provides up to 144 hours of beat-to-beat patient information from the bedside or telemetry system for parameters and waveforms. Full Disclosure also stores resting ECGs from 16 patients once per minute for 144 hours and up to 2000 alarm histories with waveform snippets for each patient. This information can be displayed at the CSCS in detailed and summary mode formats.

Intended Use: The CARESCAPE Central Station is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use is to provide clinicians with adult, pediatric and neonatal patient data within a hospital or clinical environment.

The CARESCAPE Central Station is intended to collect,

display and print information from a network, including patient demographics, physiological parameters and waveforms, alarm annunciation and/or other non-medical information from monitors and telemetry systems. Physiological parameters and waveforms include electrocardiograph (ECG), pulse oximetry (SPO2), invasive blood pressures (IBP), non-invasive blood pressure (NIBP), respiration (RR), ventilator (VNT), carbon dioxide (CO2), oxygen (O2), mass spectrometry (Gas), temperature (Temp) and bispectral index (BIS). Beat to beat patient information for parameters and waveforms from the bedside and telemetry systems can be displayed. Patient monitor and telemetry system settings can be adjusted. Parameter values derived from patient data can be calculated, displayed, and printed.

The CARESCAPE Central Station supports the ability to access information from GE products and hospital intranet in a web browser format. Additionally, CARESCAPE Central Station supports the ability to access patient information collected from the CARESCAPE network and stored on a network server.

Technology:

The CARESCAPE Central Station employs the same functional scientific technology as its predicate devices. The device is a software driven device running on a pc platform. The CARESCAPE Central Station utilizes increases in memory and a faster processor than the predecessor CIC Pro.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The CARESCAPE Central Station and its applications were tested to, and comply with, applicable voluntary standards. The CARESCAPE Central Station was tested to assure that the device meets its design specifications. Testing included all new or modified features.

The following quality assurance measures were applied to the development and testing of the of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)

- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, CARESCAPE Central Station, did not require clinical studies to support substantial equivalence.

Comparison

The following contains the differences of the CARESCAPE Central Station when compared to the predicate CIC Pro Central Station:

Hardware

- Upgraded Platform; faster CPU, more memory, refreshed design

Service and Setup

- Improvements to the user interface used by service and the installer to setup and configure the device.

Full Disclosure

- Doubled full disclosure storage amount to 144 hours.
- Added full disclosure data viewing and printing for up to 144 hours after patient discharge. Previously, after discharged the full disclosure data was unavailable.
- Added automatic collection and storage of 12SL (resting ECG) reports each minute for up to 16 patients; limited to last 144 hours.
- Added collection and storage of up to 2000 alarm histories (events) per patient for each admit-discharge episode.
- Added user entered care notes/comments per patient. Multiviewer display shows an icon if notes/comments are present.
- Added ability to search for and access patient sessions (i.e. admit-discharge episode) by name, device or MRN. Sessions hold up to 144 hours of data and may be active-admits or post-discharge.

Historical Data viewing

- Added ability to add user comments to alarm histories (events).
- Added ability to mark alarm histories as not-reviewed, reviewed, include-in-report and delete.

- Added ability for user to build a report consisting of user pre-selected alarm histories and user entered/stored comments. The report can be sent to either a laser printer or sent as a PDF file to a SFTP server (e.g. HIS, EMR, etc.)
- Added 12SL report viewer with three view modes and laser printout capability. Includes ability to send selected reports to a MUSE workstation (push to MUSE). Includes the ability to overlay median complexes of two selected reports.
- Added ST Vector magnitude trend (ST-VM) calculated from already trended ST segment deviations. This uses the ST-VM formula from 12SL V22 (K092369).

Real Time Data viewing

- Added display of ventilator operation mode (e.g. SIMV).
- Added display of ventilator waveforms.

Alarming

- Added display of the "Alarm Broadcast" text sent by a patient monitors and telemetry devices to the corresponding Multiviewer slot. Note: Alarm Broadcast text is the highest priority alarm condition as determined by the sending deice.
- Added ability to silence alarms for individual devices shown in Multiviewer slots. The previous function that silences alarms for every device shown in Multiviewer slots is still available.
- Use of IEC alarm symbols for alarm audio state and alarm priority level (i.e. bell, triangle).
- Event Marker/Remote Event changed to a low priority alarm.
- LOW/ADVISORY priority visual alarm signals appear in CYAN color in Multiviewer slots and in common alarm broadcast area (i.e. top of screen).
- INFORMATIONAL/MESSAGE priority signals appear in GRAY color in Multiviewer slots instead of no color background.
- Safety/alarm messages (e.g. UNMONITORED BED, NOT FOR PATIENT USE) moved from title bar to a common alarm broadcast area. Title bar now only shows non-alarm information.
- Separate customer changeable password added to modify alarm related settings. Originally the service

password was required.
- Modified factory presets for Telemetry alarms so the presets align with the most recent risk management process at GE Healthcare.
- Increased allowable choices for telemetry technical alarm priority level settings. Examples of the technical alarm are OFF NETWORK and LEADS OFF.
- Added IEC alarm tone set (from IEC 60601-1-8:2006). The previous (Unity) tones are available via a configuration option.
- Added alarm reminder tone. Can be disabled with password.
- Added IEC alarm priority nomenclature (HIGH, MEDIUM and LOW). User can select the old nomenclature (CRISIS, WARNING and ADVISORY) if desired.
- Added IEC informational nomenclature (INFOMATIONAL). User can select the old nomenclature (MESSAGE) if desired.

Added alarm volume current-setting indicator to top of screen

The following features are incorporated into the CARESCAPE Central Station. These features were cleared in separate 510k submissions as noted:

MUSE ST Guard (K842308)

- Acquire 12-lead reports from up to 16 devices and stores the data for up to 144 hours
- Calculates vector magnitude based on periodic ST deviation values
- Provides 1 minute trends for Vector Magnitude (ST-VM)
- View 12-lead ECG report, including curve data for ECG complexes
- Provides trend review for time of interest
- View superimposition at two selected points in time
- Ability for the clinical user to send (Push) a stored 12-lead report to the MUSE Workstation

12SL V22 (K092369)

- Added ST Vector Magnitude calculation

MUSE CV (K110132)

- Displays 10 second snippet of each ECG lead's waveform
- Displays 2.5 second snippet of each ECG lead's waveform, plus 12SL interpretative statement codes and 12SL data computations

Conclusion: GE Healthcare considers the CARESCAPE Central Station to be as safe and as effective, and its performance substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

April 30, 2014

GE Medical Systems Information Technologies, Inc.
Robert Casarsa
8200 West Tower Ave.
Milwaukee, Wisconsin 53223

Re: K133882
Trade/Device Name: CareScape Central Station (formally known as CIC Pro)
Regulation Number: 21 CFR 870.2450
Regulation Name: Central Station
Regulatory Class: Class II
Product Code: DXJ
Dated: April 15, 2014
Received: April 17, 2014

Dear Robert Casarsa,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K133882

Device Name: CARESCAPE Central Station (CSCS) – formally known as CIC Pro

Indications for Use:

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Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.04.30 13:12:08 -04'00'